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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0905]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Leroy Richardson 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

FoodNet Non-O157 Shiga Toxin-Producing *E. coli Study:* Assessment of Risk Factors for Laboratory-Confirmed Infections and Characterization of Illnesses by Microbiological Characteristics (0920-0905 expires 11/30/14) – Extension - National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year many Shiga toxin-producing *E. coli* (STEC) infections occur in the United States, ranging in severity from mild diarrhea, to hemorrhagic colitis and in some cases, life-threatening hemolytic uremic syndrome (HUS). HUS occurs most frequently following infection with serogroup O157; 6% of patients with this type of STEC infection develop HUS, with highest occurrence in children aged < 5 years. HUS has a fatality rate of approximately 5%; up to 25% of HUS survivors are left with chronic kidney damage. STEC are broadly categorized into two groups by their O antigens, STEC O157 and

non-O157 STEC. The serogroup O157 is most frequently isolated and most strongly associated with HUS. Risk factors for STEC O157 infections in the United States and internationally have been intensely studied. Non-O157 STEC are a diverse group that includes all Shiga toxin-producing *E. coli* of serogroups other than O157. Over 50 STEC serogroups are known to have caused human illness. Numerous non-O157 outbreaks have been reported from throughout the world and clinical outcomes in some patients can be as severe as those seen with STEC O157 infections, however, little is known about the specific risk factors for infections due to non-O157 STEC serogroups. More comprehensive understanding of risk factors for sporadic non-O157 STEC infections is needed to inform prevention and control efforts.

The FoodNet case-control study is the first multistate investigation of non-outbreak-associated non-O157 STEC infections in the United States. It investigates risk factors for non-O157 STEC infections, both as a group and individually for the most common non-O157 STEC serogroups. In addition, the study characterizes the major known virulence factors of non-O157 STEC to assess how risk factors and clinical features vary by virulence factor profiles. As the largest, most comprehensive, and most powerful study of its kind, it is making an important contribution towards better understanding of non-

O157 STEC infections and will provide science-based recommendations for interventions to prevent these infections. Study enrollment began between July and September 2012 (sites had staggered start dates) and is scheduled to run for 36 months. Since we have not yet enrolled enough cases to meet the study objectives, we are requesting an extension.

Persons with non-O157 STEC infections who are identified as part of routine public health surveillance and randomly selected healthy persons in the patients' communities (to serve as controls) are contacted and offered enrollment into this study. Participation is completely voluntary and there is no cost for enrollment. The total burden is 268 hours.

Estimated Annualized Burden Hours

Respondents	Form name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total
Patients	Case questionnaire	161	1	25/60	67
Controls	Control questionnaire	483	1	25/60	201
					268

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